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A STAPLE OF ANIMAL RESEARCH PROTECTIONS IS COMING SOON TO HUMAN CLINICAL TRIALS

As the academic medical establishment looks to shore up its overburdened and leaky programs for protecting the human subjects of research, they're turning to a model that's long been employed in research using animals: accreditation.

A bipartisan House bill introduced June 8 with the blessing of the academic medical establishment would mandate the establishment of a government-sanctioned accreditation program for institutional human subjects protections within two years. A tiny Boston-based nonprofit called Public Responsibility in Medicine and Research (PRIM&R) has been working on such an accreditation program for more than a year, and is likely to be the entity that's given the job.

With encouragement—but no funding so far—from the National Institutes of Health and the Food and Drug Administration, PRIM&R is now nearing completion of a set of professional standards for research involving human subjects, says Executive Director Joan Rachlin. The 28-year-old organization has long provided educational programs for institutional review boards (IRBs)—the panels of scientists and others that review clinical research protocols to ensure the protection of their human subjects. PRIM&R recently formed a new paper entity, called the Association for the Accreditation of Human Research Protection Programs.

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SCIENCE POLICY ISSUES AREN'T TOPPING BUSH'S CAMPAIGN PRIORITIES

While the battle for the White House is well underway, the campaign of George W. Bush has just begun work on its science and technology policy, say two House Science Committee veterans who are helping out.

Bob Walker, the former chairman of the science panel, and self-styled advisor to the campaign, says he was assured by Bush long ago that the Texas governor is fully committed to basic science. Walker, now chairman of the Wechsler Group, a Washington lobbying firm, told a panel during a recent American Geophysical Union meeting that more work needs to be done on the specifics of Bush's policy, and sought input from the audience of physicists.

Rep. Vernon Ehlers (R-MI) is heading a team that is recruiting scientists to provide advice on the campaign, and has submitted a draft policy statement for the campaign's review. In an interview, Ehlers said Bush told him

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that such a safety margin is excessive, but others might argue that it's too conservative and we don't have enough protection.

SGR. *Has it been determined that the 5% annual spending level is the optimal level to provide this long-term security?*

Cech. Yes. We've undertaken a strategic planning program where we have included a large number of financial projections as well as programmatic evaluations. We're about two-thirds of the way done with that process. As soon as you do these financial projections you realize that if you change the market projections a little bit, the five-year downstream effect is rather different. One of the decisions we've made is if the market continues the way it is, we are going to be announcing major new programs and major new spending initiatives almost annually over the next several years. That would be good news; we'd enjoy being able to do that.

SGR. *Will these major initiatives you speak of still have to fall within this 5% disbursement cap?*

Cech. Not necessarily. We may have to adjust the 5% and it may have to be adjusted upward if we find ourselves sitting on a \$20 billion endowment in a few years. At that point, we are not going to be limited to the 5%. The endowment has grown a lot and if it would shrink a bit for a temporary time it might make the president of HHMI a little nervous but it might be the right thing to do for awhile. We have to have our plan set, but we also are going to have to retain flexibility to respond on an annual basis, to recalibrate a bit.

SGR. *Is there a role for HHMI and other charitable providers to fund research in politically sensitive areas, for example that involving embryonic stem cells?*

Cech. There have been announcements, by the Juvenile Diabetes Foundation, for example, which is funding such research. As you know it is legal, but the derivation of stem cells is not allowable with NIH funding. If you want to get into that topic of discussion *vis a vis* HHMI, Bob Potter, our communications officer, is the one who is handling inquiries about embryonic stem cell research. We want to make sure to give a consistent response. It's a sensitive enough area that we want to give a very uniform and consistent view.

SGR. *So sensitive that the president feels uncomfortable about talking about it?*

Cech. The president likes to talk, and is still growing into the job from having been a scientist and teacher, both professions where one tends to talk a lot. Now that I'm representing HHMI, a little more care has to be taken to be sure that exactly the right words are being said.

SGR. *There are some new MROs starting up—in particular the Van Andel Research Institute and the Stowers Institute. Is there a need to coordinate what all these MROs are doing to ensure that duplication isn't occurring?*

Cech. There certainly is interest in the nonprofit community to have more communication so one can get cooperation, collaboration, some of the economy that might come

from doing things together rather than duplication of effort in some areas. And that needs to be balanced against what is the real strength of the nonprofit community, which is the diversity of approaches. The beauty of the nonprofit world is that when it's operating at its best, it can be more experimental, more risk-taking, more focused on issues of particular interest to the donors to that particular nonprofit. Yes, more communication to avoid unnecessary duplication is a good thing, but uniformity would be a bad thing. Then you'd be in the terrible situation where all of the nonprofits together, with an annual budget of only a few percent of the NIH annual budget, wouldn't have an exciting impact on the system. If they were just adding incrementally a few percent more research dollars, then if they all dried up and blew away there wouldn't be much of a negative impact.

The other neat thing about the Van Andel and Stowers institutes is that they are making a regional impact in areas where they now provide a regional medical center. They're adding a lot of vitality to Kansas City and Grand Rapids, MI. You can argue that research can be done at just a few major places. But as soon as you start thinking about the fact that there is going to be public outreach and all kinds of educational spinoffs from the research program, then it's pretty exciting to have some of these MROs operating in places like this. Is there a limit to how many MROs can operate efficiently? Maybe it would be good to have some more regional ones in places that are not the traditional powerhouses of biomedical research. Maybe that will have a very special type of impact, which would not be duplicated by simply adding additional dollars to Harvard Medical School or Stanford.

NONPROFIT PAYCHECKS: THE AMERICAN INSTITUTE OF PHYSICS

A glance at the financials of the American Institute of Physics, the umbrella organization of 10 societies representing 120,000 physicists and students, shows an organization that has nearly doubled its wealth over the past few years, with net assets exceeding \$80 million at the end of 1998.

AIP's "excess"—what the commercial world calls profit—also has risen exponentially in recent years. In 1998, the most recent year for which a return on Form 990 is available, AIP reported an excess of \$12.5 million, on revenues of \$76.8 million. In 1996, the surplus was only \$7.8 million, and the year before that, \$3.5 million.

Like many other scientific nonprofits, the bulk of AIP's revenues come from its publishing operations. Subscriptions to AIP's own journals, which include such titles as *Applied Physics Letters*, *Journal of Applied Physics*, *Journal of Chemical Physics*, and *Journal of Mathematical Physics*, and to those of its member societies, such as the American Physical Society's *Physical Review* and *Physical Review Letters*, brought in \$46.6 million in 1998. Advertising in



AIP's four magazines, which include the monthly *Physics Today* sent to all members of the constituent societies, raised another \$5 million.

Marc H. Brodsky, AIP's executive director and CEO since 1993, was paid \$246,300, plus benefits of \$28,226. That's up considerably from the \$217,931 and \$27,353 he took in during 1997, but it's still at the low end of the range of pay for the chiefs of scientific societies. Richard Nicholson, executive officer of the American Association for the Advancement of Science, made \$346,407, plus \$30,774 in benefits, during 1998, although AAAS's revenues were smaller than AIP's, at \$64.6 million. And Raymond Fowler, executive director of the American Psychological Association, was paid \$229,515, plus \$127,202 in benefits, for an operation with \$76.7 million in revenues—and which operated at a small deficit that year. No one, however, comes close to the \$605,398, plus \$36,510 in benefits that went in 1997 to American Chemical Society Executive Director John Crum, who commands an operation with revenues well over \$300 million.

Number two on the AIP pay list was Darlene Walters, vice president of AIP's publishing empire. She made \$234,936 in 1998, plus benefits of \$33,064. In 1997 she was earning \$204,346 and benefits of \$31,613.

Other officers who were paid were:

James H. Stith, director of the physics program, \$133,256 and \$12,238.

Richard Baccante, treasurer and chief financial officer, \$151,044, \$26,415. Also listed for Baccante were expenses of \$24,412.

Theresa Braun, director of human resources, \$131,254, \$20,230.

Roderick M. Grant, secretary, listed as working on an "as needed" basis, \$55,279, \$4,334.

AIP's part-time directors served without pay, benefits, or expense account.

Listed as the highest-paid employees other than officers, directors, and trustees were the following, their pay and benefits:

James Donohue, publishing services director, \$147,315, \$29,743.

Margaret Judd, information technology director, \$146,346, \$26,629.

Richard Kobel, advertising/exhibits director, \$120,183, \$21,736.

Timothy Ingoldsby, product development director, \$115,000, \$23,862.

John Scott, journal publisher, \$121,507, \$6,010.

In addition, 106 other employees, from a staff numbering 590, were paid more than \$50,000.

AIP's two largest components are the American Physical Society, with about 40,000 members, and the American Geophysical Union, with 31,800. Smaller constituents are the Optical Society of America, 11,600; Acoustical Society of America, 7,200; American Association of Physics Teach-

ers, 11,600; American Astronomical Society, 6,100; American Vacuum Society, 6,000; American Association of Physicists in Medicine, 4,300; American Crystallographic Association, 2,300; and Society of Rheology, 1,800.

Previous Paychecks In This Series

(2000): National Public Radio, June 1; Federation of American Societies for Experimental Biology, May 15; American Enterprise Institute, May 1; Biotechnology Industry Organization, April 15; University of California-operated national laboratories, April 1; American Medical Association, March 15; Association of American Universities, March 1; Heritage Foundation, February 15; American Council on Education, February 1; MITRE Corp., January 15.

(1999): American Psychiatric Association, December 15; American Association for the Advancement of Science, December 1; Association of American Medical Colleges, November 15; American Psychological Association, November 1; American Chemical Society, October 15; Howard Hughes Medical Institute, October 1; National Academy of Sciences, September 15; Massachusetts Medical Society, August 15; Cato Institute, July 15; Hudson Institute, June 15; RAND, June 1; National Education Association, May 15; American Institute of Aeronautics and Astronautics, May 1; American Cancer Society, April 15; American Heart Association, April 1; Institute of Electrical and Electronics Engineers, March 15; Center for Science in the Public Interest, March 1; American Institute of Biological Sciences, February 15; UC-operated national labs, February 1; American Geophysical Union, January 15.

JOB CHANGES & APPOINTMENTS

Rear Adm. Jay M. Cohen has been appointed the chief of naval research, succeeding **Rear Adm. Paul Gaffney**. Cohen, who most recently has headed the Navy's Y2K office, is a Naval Academy grad with a master's degree in marine engineering and naval architecture from MIT and an extensive background in submarines. Like Gaffney, Cohen will be triple hatted, holding the additional titles of director of test and evaluation and technology requirements in the office of the chief of naval operations, as well as deputy commandant for science and technology for the Marine Corps. No word at press time whether Gaffney would take a new command or retire to pursue interests in the private sector.

E. Greg Koski, an MD-PhD and director of human research affairs for Partners HealthCare System Inc., the consortium of hospitals affiliated with Harvard Medical School, has been named to direct the Office of Human Research Protection, the newly formed entity within the Department of Health and Human Services that replaces the defunct Office of Protection from Research Risks (OPRR) at the National Institutes of Health. Koski, who will formally assume

quick to issue press releases on other audits he's commissioned that have found fault with some agency under his panel's jurisdiction. This one was met with silence by the Wisconsin Republican.

Women's Health: NIH Has Increased Its Efforts to Include Women in Research (GAO/HEHS-00-96, 37 pp.), the National Institutes of Health maintains that its spending on women's health conditions grew by an inflation-adjusted 39% between 1993 and 1999, to roughly 15.5% of the total in the more recent year. GAO agreed that spending on women's health has increased more rapidly than overall NIH spending, but says it's difficult to quantify an overall percentage. Spending on osteoarthritis, depression, and mood disorders, for example, problems that disproportionately plague women, have jumped more than 70% in the period, but research on osteoporosis went up only 16%.

Occupational Safety and Health: Government Responses to Beryllium Uses and Risks (GAO/OCG-00-6, 25 pp.), the lightweight metal is used as a neutron reflector in nuclear warheads, and for other components in aircraft, spacecraft, and X-ray and laser equipment. But beryllium is hazardous, and at least 149 Energy Department workers have been diagnosed with chronic beryllium disease, an inflammatory lung condition that can be debilitating or fatal. The Occupational Safety and Health Administration is due to develop a comprehensive standard for worker exposure by next year.

Order from: GAO, PO Box 37050, Washington, DC 20013. Phone: 202-512-6000. Fax: 202-512-6061.

IN BRIEF

- The call from Chinese-American academic activists to boycott Department of Energy-run national laboratories to protest the ongoing incarceration of former Los Alamos scientist Wen Ho Lee appears to have had little impact. Applications from Asian-Americans for science and engineering positions at Los Alamos have fallen sharply since Lee's arrest last year, but the drop occurred well before a group called Asian-Pacific-Americans for Higher Education issued its call for a boycott in March. The other two nuclear weapons labs, Lawrence Livermore and Sandia, say they've seen no downturn in the numbers of Asian-American applicants.

A second organization, the Association for Asian American Studies, reiterated the boycott call early this month. DOE's ombudsman, Jeremy Wu, told *SGR* that the boycott is "counterproductive" and would have no impact on the judicial system's handling of the Lee case. The Taiwan-born scientist is charged with unlawfully transferring classified computer codes to unclassified computers, but the Asian-American groups object to his treatment, which includes solitary confinement, calling him a victim of racial profiling.

- DOE doesn't deny that racial profiling has occurred at its labs. Wu tells *SGR* that he's helped to reinstate the security clearances of six minority individuals at the labs who had their credentials yanked for what was later determined to be insufficient cause. Since a clearance is required for most jobs at the weapons labs, its revocation is tantamount to firing or demotion.

- Health and Human Services Secretary Donna Shalala pledged some financial help for the nation's struggling academic medical institutions this year. But Shalala, speaking to the June 8 Advisory Committee to the Director of the National Institutes of Health, said she wouldn't know what form the relief would take until the fiscal 2001 year budget picture for her agency becomes clearer this fall. Shalala said the Clinton administration recognizes the government will have to do more to help keep research hospitals afloat, but that simply inflating Medicare payments to hospitals was a "sloppy" fix to be avoided. The issue is complicated by the lack of uniformity in hospital-medical school relationships, and the fact that some medical centers are in worse financial shape than others, she said. Asserting that yet another study of the problem isn't needed, Shalala said a blue ribbon panel to develop a strategic plan might be warranted.

- Speaking of Medicare, the White House announcement that the program will now pick up the routine medical costs of those beneficiaries enrolling in clinical trials is expected to cost the taxpayer just \$350 million a year, Shalala said. That's because while it hasn't been explicit until now, many of those costs were already being picked up by Medicare. The new policy will create some administrative headaches for NIH: It has to define exactly what constitutes clinical research, and draft the rules that will separate routine medical costs from the clinical research costs.

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